

Patent HDAC-5005-U

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:

Group Art Unit: 1626

Jerome C. Bressi et al.

Examiner: Deborah C. Lambkin

Serial No.: 10/803,344

Filed: March 17, 2004

For: HISTONE DEACETYLASE

**INHIBITORS** 

## INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

In accordance with 37 CFR §§ 1.97 and 1.98, the items identified in this Information Disclosure Statement ("IDS") are brought to the attention of the Office. The items are listed on the attached form PTO-1449, and copies of the non-US patent references are included for the Examiner's convenience.

The items identified in this IDS may or may not be "material" pursuant to 37 CFR § 1.56. The submission thereof by Applicant is not to be construed as an admission that any such patent, publication or other information referred to therein is material or considered to be material (37 CFR § 1.97(h)), or even qualifies as "prior art" under 35 USC § 102 with respect to this invention unless specifically designated by Applicants as such.

## CERTIFICATE OF HAND DELIVERY

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being delivered via hand delivery to the Commissioner for Patents, Randolph Building, 401 Dulany Street, Alexandria, Virginia 22314.

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Signature of Person Delivering Paper

July 14, 2006 Spate of Seposit

## **INFORMATION DISCLOSURE STATEMENT FILING PROVISION:**

$\boxtimes$	This II	OS is believed to be timely in that it is being submitted under 37 CFR §				
1.97(b	), that	is (1) within three months of the filing date of the application, which is not a				
contin	ued pro	osecution application filed under § 1.53(d); or (2) within three months of				
entry o	of the n	ational stage as set forth in 37 CFR § 1.491; or (3) before the mailing of a				
first O	ffice ac	tion on the merits; or (4) before the mailing of a first Office action after filing				
a requ	est for	continued examination under § 1.114. Thus, no fee is required.				
		However, if the undersigned is in error in this regard, Applicant respectfully requests that the Office consider this IDS as filed under 37 CFR § 1.97(c), if applicable, and charge the fee due under 37 CFR §1.17(p) to the deposit account referenced below.				
		However, if the undersigned is in error in this regard, Applicant respectfully requests that the Office consider this IDS as filed under 37 CFR § 1.97(c), if applicable, and a statement under 37 CFR § 1.97(e) is included below, thus no fee is required.				
	action	OS is being submitted under 37 CFR $\S$ 1.97(c), that is after mailing of a first on the merits, but before a Final Action under 37 CFR $\S$ 1.113 or a Notice under 37 CFR $\S$ 1.311.				
		The fee due under 37 CFR § 1.17(p) is submitted herewith.				
		A statement under 37 CFR § 1.97(e) is included below, thus no fee is required. In the event that this IDS is not received before a Final Action or a Notice of Allowance, then Applicant respectfully requests that the Office consider the filing of these papers to be submitted under 37 CFR § 1.97(d) and charge the fee due under 37 CFR § 1.17(p) to the deposit account below.				
payme	37 CFF ent of th	OS is being submitted under 37 CFR § 1.97(d), that is after a Final Action R § 1.113 or a Notice of Allowance under 37 CFR § 1.311, but before he issue fee. A statement under 37 CFR § 1.97(e) is included below. The r 37 CFR § 1.17(p) is submitted herewith.				
		STATEMENT UNDER 37 CFR § 1.97(e):				
	Each i	tem contained in this IDS was first cited in any communication from a				
foreigr	paten	t office in a counterpart foreign application not more than three months				
prior to	the fil	ing of this IDS.				
	No iter	n contained in this IDS was cited in a communication from a foreign patent				
office i	ice in a counterpart foreign application, and, to the knowledge of the person signing					

this statement after making reasonable inquiry, no item of information contained in this IDS was known to any individual designated in 37 CFR § 1.56(c) more than three months prior to the filing of this IDS.

	PAYMENT AND/OR AUTHORIZATION TO CHARGE FEES:			
	A check in the amount of is enclosed for the above fee(s).			
	Please charge to Deposit Account No. 50-2256 for the above fee(s).			
	Although Applicants do not believe any fees are required, the Commissioner is rized to charge any fees required by the filing of these papers to Takeda's Deposit ant No. 50-2256.			
	Respectfully submitted,			
	TAKEDA SAN DIEGO, INC.			
Dated	By: Mitchell R. Brustein  Beg. No. 38 394			

Customer No. **32793**Takeda San Diego, Inc.
10410 Science Center Drive
San Diego, CA 92121

Tel: (858) 622-8528 Fax: (858) 550-0992

PTO/SB/08A (08-03)

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INFORMATION DISCLOSURE
STATEMENT BY APPLICANT

Application Number 10/803,344

Filing Date March 17, 2004

First Named Inventor Jerome C. Bressi

Group Art Unit 1626

Examiner Name Deborah C. Lambkin

Complete if Known

(use as many sheets as necessary)

Sheet

2

Attorney Docket Number HDAC-5005-U

U.S. PATENT DOCUMENTS					
Examiner	Cite	Document Number	Publication Date/	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant
	No.1	Number - Kind Code <sup>2</sup> (if known)	Issue Date MM-DD-YYYY	Cited Document	Passages or Relevant Figures Appear
	AA	US 5,977,108	11/2/1999	Kouichi Kikuchi et al.	
	AB	US 6,099,851	8/8/2000	Kenneth M. Weisman et al.	
	AC	US 6.541.661	4/1/2003	Daniel Delorme et al.	

		FOREIGN PA	ATENT DOCU	MENTS		
	Cite No. <sup>1</sup>	Foreign Patent Document			Pages, Columns, Lines, Where	
Examiner Initials*		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> ( <i>if known</i> )	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Relevant Passages or Relevant Figures Appear	T⁵
	AD	EP 0 354 549 A2	2/14/1990	Konica Corporation		
	AE	EP 0 378 991 A1	7/25/1990	Ciba-Geigy AG		
	AF	JP 03 289654	12/19/1991	Konica Corporation		
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	AH	EP 0570594 A	11/24/1993	SHIONOGI & CO., LTD.		
	Al	WO 97/29776 A1	8/21/1997	G.D. Searle & Co.		
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	AK	WO 01/70675	9/27/2001	METHYLGENE, INC.		
	AL	WO 02/26696	4/4/2002	PROLIFIX LIMITED		
	AM	WO 02/46129 A2	6/13/2002	Abbott Laboratories		
	AN	WO 03/024448 A2 & A3	3/27/2003	Methylgene, Inc.		
	AO	WO 03/039599 A1	5/15/2003	Novartis AG		
	AP	WO 03/066579 A2	8/14/2003	Axys Pharmaceuticals		
	AQ	WO 2004/046094	. 6/3/2004	Queen Mary & Westfield College		
	AR	WO 2005/019174	3/3/2005	Axys Pharmaceuticals, Inc.		
	AS	WO 2005/040161	5/6/2005	S*Bio PTE		
	AT	WO 2005/040101	5/6/2005	S*Bio PTE		
	AU	WO 2005/073180	8/11/2005	JKUREHA CHEMICAL INDUSTRY COMPANY, LIMITED		
	AV	EP 0 847 992 A1	6/17/1992	Mitsui Chemicals, Inc.		

Examiner	Date	
Signature	Considered	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Substitute for form 1449A/PTO				Complete if Known		
				Application Number	10/803,344	
INFORMATION DISCLOSURE				Filing Date	March 17, 2004	
STAT	STATEMENT BY APPLICANT			First Named Inventor	Jerome C. Bressi	
				Group Art Unit	1626	
(use as many sheets as necessary)		Examiner Name	Deborah C. Lambkin			
Sheet	2	of	2	Attorney Docket Number	HDAC-5005-U	

		OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS	•
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	AW	Sasho, Setsuya et al. "Preparation and formulation of thiazole derivatives as cell adhesion inhibitors" Jpn. Kokai Tokkyo Koho, 42 pp. CA 127:17674 (1997)	
-	AX	Wood, Warren J.L. et al. "Substrate activity screening: A fragment-based method for the rapid identification of nonpeptidic protease inhibitors" Journal of the American Chemical Society, (2005), 127(44), 15521-15527 143:452160	
	AY	Dai Yujia et al. "INdole amide hydroxamic acids as potent inhibitors of histone deacetylases." BIOORGANIC AND MEDICINAL CHEMISTRY LETTERS, vol. 13, no. 11, 2 June 2003 (2003-06-02), pages 1897-1901, XP002331281 ISSN; 0960-894X abstract; figures 1,2; tables 1-4	
	AZ	DATABASE BEILSTEIN INSTITUT ZUR FORDERUNG DER WISSENCHAFTEN, FRANKFURT AM MAIN, DE; 2 December 1991 (12/2/1991), XP002331282 Database accession no. 4311238 abstract	
	ВА	DATABASE BEILSTEIN INSTITUT ZUR FORDERUNG DER WISSENCHAFTEN, FRANKFURT AM MAIN, DE; 2 December 1991 (12/2/1991), XP002331283 Database accession no. 5815061 abstract	
	BB	DATABASE BEILSTEIN INSTITUT ZUR FORDERUNG DER WISSENCHAFTEN, FRANKFURT AM MAIN, DE; 2 December 1991 (12/2/1991), XP002331284 Database accession no. 7765459 abstract	
	ВС	DATABASE CAPLUS CHEMICAL ABSTRACTS SERVICE, COLUMBUS, OHIO, US; 2002 XP002325919 Database accession no. AN:2002:217200	
	BD	Lam, Patrick Y.S. et al. "Structure-based design of novel guanidine/benzamidine mimics: potent and orally bioavailable factor Xa inhibitors as novel anticogulants" Journal of Medical Chemistry (2003), 46 (21) 4405-4418, CASREACT 140; 12453	

Examiner	Date	
Signature	Considered	·

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PTO/SB/08A (08-03)

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Substitute for to 1449A/PTO Complete if Known TRADE! Application Number 10/803,344 INFORMATION DISCLOSURE Filing Date March 17, 2004 STATEMENT BY APPLICANT First Named Inventor Jerome C. Bressi Group Art Unit 1626 (use as many sheets as necessary) Deborah C. Lambkin **Examiner Name** Sheet 2 HDAC-5005-U of Attorney Docket Number

	U.S. PATENT DOCUMENTS					
Examiner	Cite	Document Number	Publication Date/	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant	
Initials *	No. Number - Kind Code <sup>2</sup> (if known)  Issue Date MM-DD-YYYY		Cited Document	Passages or Relevant Figures Appear		
	AA	US 5,977,108	11/2/1999	Kouichi Kikuchi et al.		
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	AC	US 6,541,661	4/1/2003	Daniel Delorme et al.		

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	011-	Foreign Patent Document			Pages, Columns, Lines, Where			
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l I	NFO	RMATION	DIS	CLOSURE	Filing Date	March 17, 2004	
S	STATEMENT BY APPLICANT			PPLICANT	First Named Inventor	Jerome C. Bressi	
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Sheet	2	of	2	Attorney Docket Number	HDAC-5005-U	

	OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS						
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²				
	AW	Sasho, Setsuya et al. "Preparation and formulation of thiazole derivatives as cell adhesion inhibitors" Jpn. Kokai Tokkyo Koho, 42 pp. CA 127:17674 (1997)					
	АХ	Wood, Warren J.L. et al. "Substrate activity screening: A fragment-based method for the rapid identification of nonpeptidic protease inhibitors" Journal of the American Chemical Society, (2005), 127(44), 15521-15527 143:452160					
	AY	Dai Yujia et al. "INdole amide hydroxamic acids as potent inhibitors of histone deacetylases." BIOORGANIC AND MEDICINAL CHEMISTRY LETTERS, vol. 13, no. 11, 2 June 2003 (2003-06-02), pages 1897-1901, XP002331281 ISSN; 0960-894X abstract; figures 1,2; tables 1-4					
	AZ	DATABASE BEILSTEIN INSTITUT ZUR FORDERUNG DER WISSENCHAFTEN, FRANKFURT AM MAIN, DE; 2 December 1991 (12/2/1991), XP002331282 Database accession no. 4311238 abstract					
	ВА	DATABASE BEILSTEIN INSTITUT ZUR FORDERUNG DER WISSENCHAFTEN, FRANKFURT AM MAIN, DE; 2 December 1991 (12/2/1991), XP002331283 Database accession no. 5815061 abstract					
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	ВС	DATABASE CAPLUS CHEMICAL ABSTRACTS SERVICE, COLUMBUS, OHIO, US; 2002 XP002325919 Database accession no. AN:2002:217200					
	BD	Lam, Patrick Y.S. et al. "Structure-based design of novel guanidine/benzamidine mimics: potent and orally bioavailable factor Xa inhibitors as novel anticogulants" Journal of Medical Chemistry (2003), 46 (21) 4405-4418, CASREACT 140; 12453					

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